

Johnson & Johnson

D. Nashed
TF

New Brunswick, N.J.

October 18, 1973

Subject: Epidemiological Study of
Workers in Italian Talc Mines

Dr. D. R. Petterson

On Monday, October 15, 1973, a meeting was held with Professor Giovanni Rubino, who is Director of the Institute of Industrial Medicine at the University of Turin in Italy.

In view of the increasing interest on the part of the F.D.A. in the effect of talc on health, the owners of the Italian talc mines became interested in the possibility of evaluating the health of talc workers as a means of demonstrating the lack of health hazard of talc and had asked Professor Rubino to consider possible epidemiological studies. Professor Rubino has conducted epidemiological studies on the health of industrial workers and has published on the relationship of pulmonary changes to exposure to talc.

Professor Rubino expressed an interest in helping conduct appropriate epidemiological studies in the miners in the Italian talc mines and submitted the attached suggested program for epidemiological research.

It was ascertained that Professor Rubino has in his department several physicians training to be epidemiologists as well as nurses and that these personnel could be utilized in the study. Professor Rubino is in a position to obtain all the records of the mining companies on workers who have worked in the mines since 1945 and with these records he will be able to determine who are currently working in the mines, who have left the mines and are working elsewhere, and who have died. The studies that he could conduct would relate to:

1. The Dead

In this study, the death certificates of those who have died will be located as the population in question is stable and all death certificates return to the community in which the subject was born.

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Professor Rubino believes that he can obtain the cooperation of local community officials and obtain copies of all death certificates as well as interview local physicians and families to obtain precise information on the cause of death where the data may be questionable.

All these data will be put in a computer for analysis in order to assess whether the cause of death of the miners was different from that of the national population of Italy and a control group obtained in a neighboring area where there are no talc miners. The data from the control matched group will also be placed on the computer for comparative analysis.

Professor Rubino believes that analysis of the cause of death of mine workers and a control group in the Italian national statistics could be completed with the aid of six associates by July 1, 1974. Each assistant would be paid \$400 per month and Professor Rubino believes that \$25,000 would be required to obtain the data by July 1, 1974.

2. Living Workers

In order to assess the health of current workers in the mines it would be necessary to complete a detailed case history report on each subject, conduct chest x-rays, respiratory function tests and possibly biochemical tests, and compare them with similar data on workers in other industries on which Professor Rubino has a significant amount of data. The data obtained on the workers would be computerized and compared with available data already in a data bank.

The procurement of information on current miners would be time-consuming and would take a year to accumulate and evaluate. It would cost about \$25 per subject to obtain appropriate clinical data. The cost of personal needs and statistical analysis has not been determined.

As in other mining operations the dust conditions in the Italian mines were improved in 1960 when wet mining conditions were established. As such, miners exposed prior to 1960 worked under considerably different dust conditions from those working

only since 1960. It was suggested that miners working only since 1960 should be studied initially and the data obtained should be compared with Professor Rubino's data as well as the data obtained on the Vermont miners.

Professor Rubino seemed interested and anxious to conduct epidemiological studies on the miners and would be prepared to initiate studies as soon as Johnson & Johnson defined the nature of the study needed and was prepared to cover the cost.

COMMENTARY

1. The Italian mine workers represent a comparatively large stable group of miners from whom definitive epidemiological data can be obtained as to the influence of talc on the cause of death and the effect of working in a "clean" talc mine on health where modern mining methods are utilized (i. e., since 1960). Before embarking on any studies we must determine whether further epidemiological data should be gathered in a world showing increasing interest on the effect of the environment on health.
2. It is known that the M. R. C. group in Cardiff is most anxious to do a critical epidemiological study on these Italian miners. If they can find a way to reach the group, they will certainly have such a study conducted.
3. Before any study is commenced with the Italian miners a critical protocol should be drawn up with the help of leading epidemiologists in this country who could act as consultants. The concept of consultants designing the protocols was quite acceptable to Professor Rubino.
4. Professor Rubino has a written agreement with the owners of the Italian mines that any data generated will remain confidential, and Professor Rubino was in agreement that any data generated on behalf of Johnson & Johnson would be retained as confidential unless Johnson & Johnson was interested in publishing it.
5. It is recommended that in view of the wide use of Italian talc, it would be wise to determine whether Italian talc mine workers

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die from causes that would be considered significant in relation to a control population or the Italian national population. It would also be of value to determine the health of talc workers in the mines since 1960 and correlate that with the dust exposure and the nature of the material to which they were exposed.

6. The risk/benefit ratio of conducting an epidemiological study in these mines must be considered. In order to minimize the risks someone should visit the mines, ascertain the conditions in them and interview the owners in relation to the health status of the miners.

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GHS:jd

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